

Chapter 10: Data Gaps, Uncertainty, and Professional Judgement

10.1 Introduction

Uncertainty in risk assessments is rooted in the dynamic variability associated with natural systems, the individual variability among human behavior and physiology, and the methods designed to characterize both. Risk estimates in CERCLA risk assessments are conditional on a number of assumptions made throughout the assessment. For example, a set of risk estimates may be developed for surface water ingestion based on contaminant concentrations that were modeled from a monitored up-gradient contaminant source (e.g., ground water underneath a landfill or a leaking above-ground storage tank). The numerous assumptions involved in conceptual models of environmental characterization, and the choices of what values to use in various assessment parameters, are the product of professional judgments made by the risk assessors.

Concerns raised about uncertainties and how assumptions are made in risk assessments prompted the EPA to establish programs to investigate and resolve such issues and to revise guidance documents accordingly. One of the programs established by EPA was labeled Research to Improve Health Risk Assessments (RIHRA). The program's primary objective was to identify the factors that produced the variability and uncertainty in CERCLA exposure assessments. RIHRA published a report entitled Exposure Assessment at Superfund Sites (USEPA, 1989a). In this report, RIHRA observed that deficiencies in the primary guidance documents used in preparing CERCLA risk assessments, specifically SPHEM (USEPA, 1986a) and SEAM (USEPA, 1988), were being supplemented with open scientific literature, communications with EPA headquarters, contractors, etc.

Continuing concerns raised about CERCLA exposure assumptions resulted in the creation of the EPA Superfund 30-Day Task Force to improve the effectiveness of the CERCLA program. The 30-Day Task Force published the report Accelerating Superfund Cleanups and Evaluating Risk at Superfund Sites where it recommended that CERCLA risk assessment guidance and policies be reviewed (USEPA, 1991a). In addition, to reduce the uncertainty inherent in risk assessments, the Task Force recommended that assumptions be reviewed by EPA's Office of Research and Development, the Risk Assessment Council, the Science Advisory Board, and industry and environmental groups.

EPA has recognized that risk assessments "are sometimes delayed because of the need to collect better sampling data, or negotiations with potentially responsible parties over land use, exposure assumptions, and chemical toxicity" (USEPA, 1992a). To address the need for more efficient risk assessments, CERCLA guidance documents have evolved to encompass a full description of risk balancing quantitative estimates with characterizations of uncertainty.



10.2 Discussion of Data Gaps, Uncertainty, and Professional Judgement in Statutes, Regulations and Guidelines

10.2.1 Statutes and Regulations

CERCLA, SARA, and the NCP do not provide specific guidance on how to address uncertainty characterization in baseline risk assessments. Comments to Section 300.430(d) of the 1990 NCP criticized the use of EPA's toxicity values because they incorporate uncertainty factors that overestimate levels of risk [55 FR 8711]. EPA recognized the incorporation of uncertainty factors into the toxicity values, but the agency responded that the magnitude of the uncertainty factors is based on the confidence in the toxicity studies, and are not directly related to toxicity. "Larger uncertainty factors are generally used to ensure that protective levels are identified when considering data with greater uncertainty" (USEPA, 1990a).

The preamble to the NCP points out that "the results of the baseline risk assessment are used to understand the types of exposures and risks." To better understand exposures and risks, the NCP recommends that assessors document "the sources and effects of uncertainties and assumptions on the risk assessment results" (USEPA, 1990a).

10.2.2 Guidelines

Guidance documents that were developed to support CERCLA risk assessments address uncertainty in greater detail. Guidance on how to conduct CERCLA risk assessments was initially provided in the Superfund Public Health Evaluation Manual (SPHEM) (USEPA, 1986a). Later, SPHEM was revised and published as Risk Assessment Guidance for Superfund (RAGS) (USEPA, 1989b). In addition to SPHEM and RAGS, EPA developed further guidance supporting CERCLA risk assessments, specifically the Superfund Exposure Assessment Manual (SEAM) (USEPA, 1988), the Exposures Factors Handbook (EFH) (USEPA, 1989c), and various exposure assessment guidelines (USEPA, 1986b; 1992b). These guidance documents acknowledge the existence of data gaps and the uncertainty resulting from those data gaps, as well as from the various assumptions made to fill these gaps. Following is a discussion of how each guidance document addresses uncertainty in risk assessments and how they have contributed to a greater understanding of the issue.

Guidelines for Estimating Exposures

The Federal Register of September 24, 1986, (USEPA, 1986b) published the EPA Guidelines for Estimating Exposures, as well as the EPA responses to comments from the public and the EPA Scientific Advisory Board (SAB). The guidelines, which provide EPA with a framework for performing exposure assessments, indicated that the ideal exposure assessment would be based on data derived from environmental measurements, but recognized that data gaps would be a common problem. When environmental data are limited, EPA directs assessors to use modeling to estimate exposures, and to use properly identified assumptions and "order of magnitude estimates" to delineate exposure areas of concern (USEPA, 1986b).



The guidelines state that uncertainty evaluation is an important part of all exposure assessments because both data and assumptions carry varying degrees of uncertainty that impact the accuracy of the assessment. The method used for assessing uncertainty depends on several factors including the underlying parameters being estimated the type and extent of available data, and the estimation procedures used. If the data used in the exposure assessment were a result of statistical modeling, justification of the model should be included. The guidelines recognize the existence of uncertainties in measurements of environmental contamination, and in the estimation of those concentrations when direct measurements are unavailable, and state that “reliable, analytically-determined values must be given precedence over estimated values” (USEPA, 1986b).

The guidelines contain a section of EPA responses to public comments on the proposed guidelines. Commentors expressed concern that the guidelines allowed assessors “too much latitude in choice of approach and do not assure that all data, sources, limitations, etc. are considered before an exposure assessment is conducted.” EPA replied that the generality of the guidelines is deliberate “in order to accommodate the development of exposure assessments with different levels of detail depending on the scope of the assessment.” Other commentors asked for further guidance to address situations where different exposure models give different results. The EPA indicated the necessity of evaluating the uncertainties associated with source data and assumptions, “whether the exposure assessment is based on measurements or simulation model estimates” (USEPA, 1986b). The EPA also replied to concerns that worst-case estimates would be used when data are limited or nonexistent “The guidelines do not encourage the use of worst-case assessments, but rather the development of realistic assessments based on the best data available” (USEPA, 1986b). However, the guidelines emphasize that EPA will err on the side of public health when evaluating uncertainties if data are limited or nonexistent.

Superfund Public Health Evaluation Manual (SPHEM)

The Superfund Public Health Evaluation Manual (SPHEM) provides detailed guidance on how to conduct a public health evaluation at a Superfund site. SPHEM did not explicitly address uncertainty in risk assessments, but it did call for a listing of the most significant factors increasing the uncertainty of the risk assessment. Because the actual dose received is generally uncertain, the exposure assessment requires the use of complex exposure models that are based on incomplete knowledge of how hazardous substances are transported and undergo transformation in the environment and how they affect human health. SPHEM indicates that the most appropriate models for Superfund sites are “simple environmental fate models using conservative (i.e., reasonable worst case) assumptions.”

Exposure assessments performed under SPHEM were directed toward estimating a range of exposure scenarios a best estimate and an upper-bound scenario. According to SPHEM, this approach would provide “not only an estimate of the risk magnitude but also a good indication of the overall uncertainty of the analysis” (USEPA, 1986a).

Superfund Exposure Assessment Manual (SEAM)

SEAM provided guidance for assessing contaminant release, environmental fate and transport, and human exposure to contaminants emanating from hazardous waste sites. SEAM was developed to give



consistency in conducting exposure assessments at Superfund sites. It compiled and integrated various methodological approaches published by EPA and others.

On communicating the uncertainty associated with the estimated level of risk, SEAM recommends including a standard deviation or the 95% confidence limit. As indicated in the earlier Guidelines for Estimating Exposures, SEAM also suggested that “further research was needed on the use of a distributional approach to characterize exposure uncertainty” (USEPA, 1988).

EPA Region I Supplemental Guidance

EPA Region I (Connecticut Maine, Massachusetts, New Hampshire, Rhode Island, Vermont) released the Region I Supplemental Manual to Risk Assessment Guidance for the Superfund Program (USEPA, 1989d). The EPA Region I Guidance indicated that uncertainties and limitations are addressed in the final section of the risk assessment. According to this guidance, the final section “should clearly state the major limitations, sources of uncertainty, and, if possible, provide an indication as to whether they have resulted in over- or under-estimations of risk.” Following are examples of uncertainties and limitations:

- sample data that may tend to bias results (e.g., adverse weather conditions, heterogeneity of sample data),
- methodology used to compile and analyze the data (e.g., detection limits not documented),
- reliance upon non-validated models that predict contaminant fate and transport,
- variations in human behavior, and
- dose-response uncertainties (e.g., extrapolation of potency across routes of exposure, application of potency estimates to mixtures).

EPA Region I guidance called for a greater imperative to communicate and substantiate exposure assumptions and choice of exposure parameters. It also recommended a sensitivity analysis to determine which parameters have the greatest influence on the resulting risk estimates. Region I guidance provided for a set of default exposure parameters and recommended more communication with EPA remediation project managers.

The Exposure Factors Handbook (EFH)

The EPA’s guidelines for estimating exposures, as delineated in SEAM, were expanded and improved in the Exposure Factors Handbook (EFH) (USEPA, 1989c). The guidelines were developed to promote consistency among the various exposure assessment activities and toward standardizing exposure assessment calculations. The handbook demonstrates how to apply standard default factors to specific exposure scenarios when site-specific data are not available. This handbook was intended to serve as a



support document to EPA's 1986 Guidelines for Estimating Exposures. It provides basic equations for estimating exposure for various exposure scenarios.

The EFH points out that the analyst "needs to be aware of uncertainties that result from using conservative assumptions when data are lacking," and that, when it is not feasible to acquire measured release rates, estimates could be made based on contaminant concentration measurements in relevant source media (e.g., ground water contaminant concentration estimation based on measured contaminated soil concentrations) (USEPA, 1989c). EFH also describes approaches for dealing with uncertainty (e.g., sensitivity appraisals, Monte-Carlo simulations, and use of monitoring data to calibrate the model).

The EHF illustrated that the analyst is expected to have "a strong technical background in engineering or the sciences" and that it may be necessary for the analyst to obtain and use the original source documentation for the analytical methods. It also cautioned that care should be taken when interpreting modeling results because of the additive effect of using many conservative assumptions. The EHF also stated that "the U.S. EPA encourages ongoing communication between site analysts and experts in various exposure and health impact assessment fields."

Risk Assessment Guidance for Superfund, Volume I (RAGS)

RAGS, published in December of 1989, provides the current conceptual framework to be used when conducting CERCLA risk assessments. RAGS admits not being able to provide guidance to all circumstances arising at a site. RAGS states that users of the manual "must exercise technical and management judgment, and should consult with EPA regional risk assessment contacts" (USEPA, 1989b). RAGS emphasizes the appropriateness of the personnel involved in conducting the risk assessments because various assumptions and judgments are required during the process. RAGS recognizes the following general types of uncertainties associated with risk assessments:

- selection of contaminants of concern,
- chemical monitoring data (sampling and analysis),
- chemical fate modeling,
- exposure intake parameters,
- toxicity values, and
- summing exposure intakes across multiple pathways.

RAGS describes how to summarize and discuss the uncertainties in (1) site-specific exposure assessments and (2) general toxicity evaluations. Regarding exposure assessments, RAGS identified the following components responsible for uncertainties:



- Definition of physical setting: Characterization of the physical setting involves many professional judgments and assumptions about land uses, exposure pathways, and selection of contaminants of concern.
- Model applicability and assumptions: The mathematical expression of an exposure model (ground water transport model) is an approximation of site-specific environmental conditions. Because the currently available models are only partially validated and employ various simplifying assumptions, the risk estimates will be impacted by the uncertainties in the models. Characterizing model uncertainties involves (1) listing/summarizing key model assumptions and (2) indicating the direction and magnitude of the impact of the model (i.e., whether it overestimates or underestimates the risk levels and by how much).
- Exposure parameter value uncertainty: Significant site data gaps require that assumptions be made for certain parameters. Characterizing parameter uncertainties involves (1) listing all key exposure parameters (e.g., body weight, exposure duration, etc.); (2) describing the measured or assumed parameter distributions, including the shape of the distribution (e.g., log-normal), mean (geometric or arithmetic), total range, and percentiles; and (3) presenting parameter uncertainties in graphic form.

Regarding toxicity assessments, RAGS delineated the characterization of toxicity uncertainties as encompassing:

- listing weights-of-evidence for carcinogens,
- presenting how the data were derived (e.g. human or animal studies, duration of study, etc.),
- listing extrapolations from less-than-lifetime exposures to lifetime cancer risks,
- presenting information on potential synergistic or antagonistic interactions, and
- presenting qualitative information for each substance not included in quantitative assessment.

Guidance for Data Useability in Risk Assessment (GDURA)

Guidance for Data Useability in Risk Assessment (GDURA) was published to present an overview of the data collection and evaluation issues that affect the quality and usability of risk assessments (USEPA, 1990b). This guidance discusses how the quality of environmental data impacts the level of certainty of the risk assessment and stresses the importance of analyzing data limitations during the risk characterization. The document reviews the issues affecting the level of confidence in each component of the risk assessment.



To address uncertainties during hazard identification, GDURA indicates the need for describing the degree of confidence associated with the analytical sampling and analyses. In relation to uncertainties in exposure assessments, GDURA recommends (1) presenting the range of values for the chemicals monitored and the factors used in developing intake estimates and (2) summarizing the major assumptions made and how they affect the final exposure. During the toxicity assessment, GDURA indicates the importance of providing the degree of confidence on toxicity values (i.e., weight-of-evidence for cancer slopes, and uncertainty and modifying factors for RfDs). Finally, GDURA recommends that assessors provide an overview of the methods used for uncertainty analysis and include, along with numerical results, statements regarding limitations and uncertainties.

Supplemental Guidance to RAGS: Standard Default Exposure Factors

An EPA risk assessment intra-agency group was formed in March of 1990 “to address concerns regarding inconsistencies among exposure assumptions in Superfund risk assessments,” and released an interim final document entitled Supplemental Guidance to RAGS: Standard Default Exposure Factors (USEPA, 1991b). According to the EPA intra-agency group, there are two main reasons for exposure assessment inconsistencies:

- professional judgment when choosing values for key variables and
- assumptions based on limited data.

The document provides further guidance on which specific default exposure factors to use when site-specific data are unavailable. It also states that “for factors where there is a great deal of uncertainty, a rationally-derived conservative estimate is developed and explained” (USEPA, 1991b).

Exposure Assessment Methods Handbook (EAMH)

The Exposure Assessment Methods Handbook was published to provide guidance to exposure assessors on methodologies for estimating concentrations of chemicals in the environment (USEPA, 1991c). This document dedicates a chapter to Characterization and Analysis of Uncertainties in the Sampling, Monitoring, and Modeling of Environmental Concentrations of Contaminants. This chapter indicates that analysis of uncertainties can “provide decision makers with the complete spectrum of information concerning the quality of a concentration estimate, including the potential variability in the estimated concentration, the inherent variability in the input parameters, the existence of data gaps, and the effect those data gaps have on the accuracy or reasonableness of the concentration estimates developed” (USEPA, 1991c). The handbook identifies six causes of uncertainty in exposure assessments:

- Measurement errors: Uncertainty caused by random and systematic errors in measurement techniques (e.g., chemical analysis).
- Indirect empirical or generic data: Uncertainty caused by applying indirect data (e.g., use of a structurally similar chemical where chemical-specific data is lacking).



- Variability of natural systems: Uncertainty caused by inherent random variability in environmental- and concentration-related parameters (e.g., river flow, wind speed, ingestion rate, etc.).
- Environmental modeling: Uncertainty caused by simplifying approximations required in mathematical algorithms.
- Sampling errors: Uncertainty caused by sampling selection, number of samples, sample accuracy and precision, and sampling frequency.
- Professional judgement: Uncertainty caused by using professional judgments in every step of the assessment (e.g., evaluation of information, interpretation of results, etc.).

After identifying uncertainties, assessors are recommended to qualitatively and quantitatively analyze the impacts of these uncertainties on the estimation results. The qualitative analysis includes “a listing of possible variations in each parameter that would encompass a reasonable range of actual expected concentration conditions,” and a statement of the impact of pertinent assumptions. A qualitative analysis should “transmit the level of confidence in the results to the decision maker and aid in determining future actions.” For a quantitative analysis, the handbook identifies the following methods: (1) sensitivity analysis, (2) mean and variance of concentrations, (3) Monte Carlo simulation, and (4) confidence interval for concentration characteristics.

Finally, the handbook stresses the importance of how the results of uncertainty analyses are presented. The presentation should include the identification of the most sensitive parameters, statements of qualitative and quantitative uncertainties, major data gaps, and summary of the uncertainties for the overall concentration estimation.

Guidance for Risk Assessment

This document was released as part of a February 1992 memorandum from EPA Deputy Administrator Henry Habicht. The memorandum directs that the risk characterization section of the risk assessment must identify important uncertainties as a “discussion on confidence in the assessment.” He further directs that “the uncertainty analysis should reflect the type and complexity of the risk assessment, with the level of effort for analysis and discussion of the uncertainty corresponding to the level of effort for the assessment” (USEPA, 1991d). Finally, Habicht also stressed that when scientific assumptions are used, they need to be discussed, along with implications of using alternative assumptions.

Supplemental Guidance to RAGS: Calculating the Concentration Term

This supplemental guidance was designed to explain how assessors should calculate the concentration term to be used in exposure intake equations under the framework of the reasonable maximum exposure (RME). The supplemental guidance states that the RME “is intended to account for both variability in exposure parameters and uncertainty in the contaminant concentration” (USEPA, 1992c). It defines the concentration term as the result of the calculation of the 95% upper confidence limit (UCL)



on the arithmetic average (mean) of the environmental samples. The rationale for using the 95% UCL value is that statistical confidence limits are “the classical tool for addressing uncertainties of a distribution average” (USEPA, 1992c).

Guidelines for Exposure Assessment

The Guidelines for Exposure Assessment, published in response to recommendations from EPA's SAB and the general public (USEPA, 1992b), replaced the Guidelines for Estimating Exposures published in 1986 and the Proposed Guidelines for Exposure-Related Measurements published in 1988. The guidelines outline the current theoretical principles to be used for exposure assessments in the CERCLA program.

Specifically, the guidelines introduce uncertainty “characterization” and uncertainty “assessment” as two activities that lead to varying degrees of sophistication in describing uncertainty. According to the guidelines, the characterization phase involves a qualitative discussion of the decisions that lead to the selection and rejection of specific data. The assessment phase is more quantitative in nature and may involve simple measures and techniques, such as ranges and sensitivity analysis, or more complex quantitative methodologies, such as probabilistic uncertainty analysis. For the less complex exposure assessments, where quantitative information is limited, the guidelines indicated that the uncertainty characterization may be all that is necessary.

The Guidelines for Exposure Assessment provides several options for dealing with data gaps

- collect new data,
- narrow the scope of the assessment where possible,
- use conservative assumptions,
- utilize models to estimate the conservativeness of assumptions,
- make use of applicable surrogate data, or
- utilize professional judgement,

The Guidelines for Exposure Assessment states that “the utility of [professional judgement] depends on the confidence placed in the estimate. Expert opinion based on years of observation of similar circumstances usually carries more weight than anecdotal information. The assessor must discuss the implications of these estimates in the uncertainty analysis” (USEPA, 1992b).



10.3 Issues and Regulator Dialogue

10.3.1 Data Gaps, Uncertainty, and Professional Judgement Issues

Review of CERCLA guidance documents reveals that there are numerous sources of uncertainty involved in evaluating human health risks from exposures to contaminants emanating from hazardous waste sites. EPA has declared that “no risk assessment is certain,” and that the function of a risk assessment is to provide “a best estimate of potential current and future risk along with the limitations associated with the estimates” (USEPA, 1990b).

Uncertainty analysis is the last step in the risk characterization. However, the analysis of uncertainty is a required procedure in every component of the risk assessment (i.e., during hazard identification, exposure assessment, toxicity assessment, and risk characterization). In the 1986 Guidelines for Estimating Exposures, EPA encouraged the evaluation of uncertainty in each aspect of the exposure assessment and stressed the importance of estimating the level of uncertainty in risk assessments so that decisions based on the risk assessment will reflect total uncertainty. However, RAGS states that “even in the most comprehensive analyses, it will generally be true that not all of the sources of uncertainty can be accounted for” (USEPA, 1989b). Nevertheless, insofar as possible an indication of the likely impact of uncertainties on the risk estimates obtained also should be provided (i.e., an indication of whether the uncertainties tend to drive risk estimates up or down). To date, however, risk assessors often have not provided such insight to decision makers. In a recent review and analysis of the degree to which risk assessments were adhering to the guidance provided by EPA Headquarters, the General Accounting Office reported that in 19 out of 20 baseline risk assessments reviewed did not adequately follow EPA’s guidance for disclosure of uncertainties in the assessment (GAO, 1994). Of the 20 assessments, 18 failed to include information on the possible ranges of values for various exposure parameters, 10 did not indicate how the uncertainties in the assessment affected the risk estimates obtained, and 7 did not provide the basis for selection of values or assumptions.

Exposure Assumptions and Toxicity Values are Great Sources of Uncertainty

Regarding the relative impact of data gaps, uncertainties, and assumptions made during the four components of a CERCLA risk assessment, EPA has stated that “uncertainties in toxicological measures and exposure assessments are greater than uncertainties in environmental analytical data and usually have a more significant effect on the uncertainty of the risk assessment” (USEPA, 1990b). The guidelines for exposure assessment, as delineated in SEAM, the Exposure Factors Handbook, the Guidelines for Exposure Assessment, and other documents, were developed to promote consistency among EPA exposure assessment activities. However, EPA has often revised the parameters used in exposure intake calculations to correspond with new policies and default factors to be followed in CERCLA risk assessments. Thus, the methodology used to assess exposure can introduce uncertainty in the overall risk assessment.

It is important to acknowledge the uncertainties in toxicity values because the exposure intake estimates are compared to them in the risk characterization step. Since human data seldom are available or adequate to estimate the toxicity values, risk estimates are generally based on experimental animal results. Cancer slope factors and reference doses in the EPA IRIS database are, for the most part, derived



from animal toxicological studies. Extrapolation from animal to human populations results in considerable uncertainty. It is believed that the use of uncertainty factors in performing the extrapolation overestimates the risk although the following statement reflects another option:

For chemicals where the dose-response is nearly linear below experimental doses, cancer risk estimates based on animal data are not necessarily conservative; Supralinearity could lead to anticonservative estimates of cancer risk...If the dose-response is nonlinear at low doses to produce cancer risks near zero, then low-dose estimates based on linear extrapolation are likely to overestimate risk and the limits of uncertainty cannot be established (Gaylor et al., 1993).

Uncertainties Tend to Overestimate Risk

Table 10.1 provides an overview of the typical sources of uncertainties associated with the various components of the risk assessment, and the impact of various assumptions required to address data gaps. Review of CERCLA guidance documents indicates that uncertainties associated with the ‘numerous assumptions made during the various phases of the risk assessment most frequently tend to overestimate the levels of risk associated with CERCLA sites.

Table 10.1: Typical Sources of Uncertainty in CERCLA Risk Assessments

Data Gaps/Uncertainty	Assumptions	Impact on Risk Assessment
Hazard Identification		
Insufficient number of samples	Use of various estimation methods	Overestimation
High detection limits	Contaminant level below detection limit	Underestimation
Contaminant degradation during sampling	Degradation occurs	Underestimation
Exposure Assessment		
Limited information on intake factors, population characteristics, exposure duration, etc.	Various assumptions required	Overestimation and/or underestimation



Data Gaps/Uncertainty	Assumptions	Impact on Risk Assessment
Limited or no chemical bioavailability data	100% bioavailability	Overestimation
Limited or no data on degradation, transformation, and fate of chemicals	No degradation and/or transformation	Overestimation and/or underestimation
Limited dermal absorption factors	Conservative default factors	Overestimation
Toxicity Assessment		
Toxicity values for low doses in humans derived from high doses in animal studies	Linearity of dose-response curves at low doses	Overestimation and/or underestimation
Limited information on shape of carcinogenic dose-response curves at low doses	95% upper confidence limit on cancer slope factors	Overestimation
Risk Characterization		
No toxicity information on individual chemicals	Use of RfDs and cancer slope factors of similar chemicals	Overestimation
No toxicity information on individual chemicals	Not factored into quantitative analysis	Underestimation
No interactive toxicity information on mixtures of chemicals	Dose additivity	Overestimation if antagonistic interaction; underestimation if synergistic interaction
Limited quality and size of sources of information	Quantification of risks, but no quantitative analyses of uncertainty possible	Risk assessment open to differing interpretations



Limited Prescribed Protocols to Address Uncertainty

The guidance documents reviewed suggest various procedures for addressing uncertainties. For example, methods exist to assess uncertainty and sensitivity in mathematical models (e.g., differential analysis, response-surface replacement, Monte Carlo methods). However, EPA suggestions are mostly general and do not provide for a specific methodology.

To address the uncertainty encountered in CERCLA risk assessments, RAGS recommends that the risk assessor “fully specify the assumptions and uncertainties inherent in the risk assessment to place the risk estimates in proper perspective” (USEPA, 1989b). EPA recommends a qualitative and/or a semi-quantitative approach that dictates “it is more important to identify the key site-related variables and assumptions that contribute most to the uncertainty than to precisely quantify the degree of uncertainty in the risk assessment” (USEPA, 1989b). Because of the considerable resources required under current practices to enable valid probability data distributions, EPA recognizes that “highly quantitative analysis is usually not practical or necessary” (USEPA, 1989b).

Use of Professional Judgement

Every CERCLA guidance document recommends the use of the best professional judgement when data gaps are encountered in the risk analysis. Because uncertainties inherent in risk assessments can produce a wide range of risk estimates, risk assessors have to make choices among numerous possibilities. According to William Ruckelshaus, former EPA Administrator, “[S]uch choices are influenced by values, which may be affected by professional training, or by ideas about what constitutes good science” (USEPA, 1984). EPA values, rooted in the various congressional mandates to be protective of public health, are biased toward the use of conservative models when data are lacking. This protective bias has often been criticized for producing unrealistic risk estimates, and also for impractical mandates “EPA often has a hard time dealing with uncertainty because personnel with different professional background operate under different statutes, which prompt different attitudes towards uncertainty...The agency cannot develop a rationale and consistent program without agreement on how to handle uncertainty. It must do better in clarifying the often subtle line between science and policy” (CEQ, 1985).

10.3.2 Regulator Dialogue

CERCLA risk assessment guidance documents acknowledge that uncertainties in risk assessments are in part the product of a lack of scientific knowledge (USEPA, 1989b; 1991c). The 16th Annual Report of the Council on Environmental Quality (CEQ, 1985) observes that “scientific uncertainty is pervasive in environmental decision-making,” and that “scientific issues concerning environmental protection often wind up for resolution in a courtroom rather than a laboratory because most of EPA mandates demand decisions for which no firm scientific basis exists.” The decisions, choices, and assumptions made by the various individuals requiring the best professional judgement may result in disparate conclusions.

A Carnegie Foundation publication reports that risk assessment is “a tool for extrapolating from scientific data to a risk number,” using assumptions that are “an admixture of science and policy”



(Carnegie, 1993). The report adds that “the science underlying most risk assessment assumptions is inconclusive,” and relying on those assumptions produces numerical risk estimates that are “highly uncertain and highly variable.” The report also indicates the difficulty in gaining a consensus about science and policy, and concludes that because “the process is assumption-and-value-laden,” its usefulness depends on the understanding of its assumptions and limitations.

In conclusion, data gaps and uncertainty are an integral part of CERCLA risk assessments. Dealing with data gaps and uncertainty may require the use of general default values (usually conservative), the use of mathematical models, or use of assumptions based on professional judgement. Regardless of which method or combination of methods are used to derive quantitative estimates of risk, it is imperative that the sources of uncertainty be clearly documented and evaluated. However, the lack of clear protocols on how to evaluate uncertainty may result in inconsistencies in the application of judgments, resulting in risk assessments being developed differently among CERCLA sites.

The above discussion, and discussions in previous chapters, illustrates that data gaps, uncertainties, and professional judgement are inherent in risk assessments. One method that can be used to remove data gaps is to obtain more site- or chemical-specific information. This information may not always be obtainable, therefore, models will have to be used. The DOE risk assessor should be knowledgeable about the site conditions and all potential exposure models, and input parameters for those models. Because of differing site conditions, no one model will be appropriate for all DOE sites. A thorough knowledge of site conditions and models will enable the risk assessor to determine which model, and input parameters, are most appropriate for a particular site. This knowledge will also enable the assessor to negotiate with EPA as to why certain models and parameters were chosen for that site. Choosing the most appropriate models and input parameters should also help to lower the uncertainty in the risk calculation.

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